

AMENDED IN ASSEMBLY MAY 15, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 1727

Introduced by Assembly Member Rodriguez

February 14, 2014

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1727, as amended, Rodriguez. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy that is owned by, or contracts with, the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards is eligible for donation to the repository and distribution program. Existing law also prohibits the donation of controlled substances to the repository and distribution program.

This bill would also prohibit the donation to a county repository and distribution program of a ~~prescription drug that can be dispensed only to a patient registered with the drug's manufacturer in accordance with the requirements of the~~ *medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy that restricts that inventory transfer.*

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California

1 State Board of Pharmacy prohibits an eligible or participating
2 entity from participating in the program, it shall provide written
3 notice to the prohibited entity within 15 days of making this
4 determination. The county board of supervisors, the public health
5 officer of the county, and the California State Board of Pharmacy
6 shall ensure that this notice also is provided to one another.

7 (b) A county that elects to establish a repository and distribution
8 program pursuant to this division shall establish written procedures
9 for, at a minimum, all of the following:

10 (1) Establishing eligibility for medically indigent patients who
11 may participate in the program.

12 (2) Ensuring that patients eligible for the program shall not be
13 charged for any medications provided under the program.

14 (3) Developing a formulary of medications appropriate for the
15 repository and distribution program.

16 (4) Ensuring proper safety and management of any medications
17 collected by and maintained under the authority of a participating
18 entity.

19 (5) Ensuring the privacy of individuals for whom the medication
20 was originally prescribed.

21 (c) Any medication donated to the repository and distribution
22 program shall comply with the requirements specified in this
23 division. Medication donated to the repository and distribution
24 program shall meet all of the following criteria:

25 (1) The medication shall not be a controlled substance.

26 ~~(2) The medication shall not be a prescription drug that can be~~
27 ~~dispensed only to a patient registered with the drug's manufacturer~~
28 ~~in accordance with the requirements of the United States Food and~~
29 ~~Drug Administration.~~

30 ~~(3)~~

31 (2) The medication shall not have been adulterated, misbranded,
32 or stored under conditions contrary to standards set by the United
33 States Pharmacopoeia (USP) or the product manufacturer.

34 ~~(4)~~

35 (3) The medication shall not have been in the possession of a
36 patient or any individual member of the public, and in the case of
37 medications donated by a health or care facility, as described in
38 Section 150202, shall have been under the control of a staff
39 member of the health or care facility who is licensed in California

1 as a health care professional or has completed, at a minimum, the
2 training requirements specified in Section 1569.69.

3 (d) (1) Only medication that is donated in unopened,
4 tamper-evident packaging or modified unit dose containers that
5 meet USP standards is eligible for donation to the repository and
6 distribution program, provided lot numbers and expiration dates
7 are affixed. Medication donated in opened containers shall not be
8 dispensed by the repository and distribution program and once
9 identified, shall be quarantined immediately and handled and
10 disposed of in accordance with the Medical Waste Management
11 Act (Part 14 (commencing with Section 117600) of Division 104).

12 (2) *A medication that is the subject of a United States Food and*
13 *Drug Administration managed risk evaluation and mitigation*
14 *strategy pursuant to Section 355-1 of Title 21 of the United States*
15 *Code may be donated only if this inventory transfer is not restricted*
16 *by that strategy, and shall be managed and dispensed according*
17 *to the requirements of that strategy.*

18 (e) A pharmacist or physician at a participating entity shall use
19 his or her professional judgment in determining whether donated
20 medication meets the standards of this division before accepting
21 or dispensing any medication under the repository and distribution
22 program.

23 (f) A pharmacist or physician shall adhere to standard pharmacy
24 practices, as required by state and federal law, when dispensing
25 all medications.

26 (g) Medication that is donated to the repository and distribution
27 program shall be handled in the following ways:

28 (1) Dispensed to an eligible patient.

29 (2) Destroyed.

30 (3) Returned to a reverse distributor or licensed waste hauler.

31 (4) (A) Transferred to another participating entity within the
32 county to be dispensed to eligible patients pursuant to this division.
33 Notwithstanding this paragraph, a participating county-owned
34 pharmacy may transfer eligible donated medication to a
35 participating county-owned pharmacy within another adjacent
36 county that has adopted a program pursuant to this division, if the
37 pharmacies transferring the medication have a written agreement
38 between the entities that outlines protocols and procedures for safe
39 and appropriate drug transfer that are consistent with this division.

1 (B) Medication donated under this division shall not be
2 transferred by any participating entity more than once, and after
3 it has been transferred, shall be dispensed to an eligible patient,
4 destroyed, or returned to a reverse distributor or licensed waste
5 hauler.

6 (C) Medication transferred pursuant to this paragraph shall be
7 transferred with documentation that identifies the drug name,
8 strength, and quantity of the medication, and the donation facility
9 from where the medication originated shall be identified on
10 medication packaging or in accompanying documentation. The
11 document shall include a statement that the medication may not
12 be transferred to another participating entity and must be handled
13 pursuant to subparagraph (B). A copy of this document shall be
14 kept by the participating entity transferring the medication and the
15 participating entity receiving the medication.

16 (h) Medication that is donated to the repository and distribution
17 program that does not meet the requirements of this division shall
18 not be distributed or transferred under this program and shall be
19 either destroyed or returned to a reverse distributor. This
20 medication shall not be sold, dispensed, or otherwise transferred
21 to any other entity.

22 (i) Medication donated to the repository and distribution program
23 shall be maintained in the donated packaging units until dispensed
24 to an eligible patient under this program, who presents a valid
25 prescription. When dispensed to an eligible patient under this
26 program, the medication shall be in a new and properly labeled
27 container, specific to the eligible patient and ensuring the privacy
28 of the individuals for whom the medication was initially dispensed.
29 Expired medication shall not be dispensed.

30 (j) Medication donated to the repository and distribution program
31 shall be segregated from the participating entity's other drug stock
32 by physical means, for purposes including, but not limited to,
33 inventory, accounting, and inspection.

34 (k) A participating entity shall keep complete records of the
35 acquisition and disposition of medication donated to, and
36 transferred, dispensed, and destroyed under, the repository and
37 distribution program. These records shall be kept separate from
38 the participating entity's other acquisition and disposition records
39 and shall conform to the Pharmacy Law (Chapter 9 (commencing

1 with Section 4000) of Division 2 of the Business and Professions
2 Code), including being readily retrievable.

3 (l) Local and county protocols established pursuant to this
4 division shall conform to the Pharmacy Law regarding packaging,
5 transporting, storing, and dispensing all medications.

6 (m) County protocols established for packaging, transporting,
7 storing, and dispensing medications that require refrigeration,
8 including, but not limited to, any biological product as defined in
9 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
10 an intravenously injected drug, or an infused drug, shall include
11 specific procedures to ensure that these medications are packaged,
12 transported, stored, and dispensed at appropriate temperatures and
13 in accordance with USP standards and the Pharmacy Law.

14 (n) Notwithstanding any other provision of law, a participating
15 entity shall follow the same procedural drug pedigree requirements
16 for donated drugs as it would follow for drugs purchased from a
17 wholesaler or directly from a drug manufacturer.